IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG,	)	
Plaintiffs,	)	C.A. No. 23-685 (CFC)
v.	)	REDACTED - PUBLIC VERSION
APOTEX INC. and APOTEX CORP.	)	
Defendants.	)	

PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS

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I. NATURE AND STAGE OF THE PROCEEDING

Plaintiffs/Counterclaim Defendants Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, Boehringer Ingelheim Corporation, and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, "Boehringer" or "Plaintiffs"), respectfully submit this Opposition to Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex")'s Rule 12(c) Motion for Judgment on the Pleadings (D.I. 26-27).

II. SUMMARY OF ARGUMENT

Before the parties even begin discovery, Apotex asks the Court to find it does not and will not infringe as a matter of law. Apotex urges the Court to accept its interpretation of the facts, and discard Boehringer's, on issues deeply entangled in factual disputes, including: whether Apotex's generic label ("Label") contains instructions that lead healthcare providers to infringe; whether clinicians would view Apotex's Label as encouraging or promoting infringing use; and the significance of the alleged non-infringing use. Boehringer's interpretation of Apotex's Label is plausible, and that is enough at this stage. Apotex's motion should be denied.

First, on induced infringement, Apotex's assertion that its Label does not encourage infringement is both factually and legally flawed. For patents on methods of treatment involving a drug product, "[t]he pertinent question is whether the proposed label instructs users to perform the patented method." *AstraZeneca LP v.*

Apotex, Inc., 633 F.3d 1042, 1060 (Fed. Cir. 2010). "[E]vidence that the product labeling that Defendants seek ***would inevitably lead some physicians to infringe*** establishes the requisite intent for inducement". *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017) (emphasis added). Apotex's Label contains comprehensive instructions for administering linagliptin to patients with severe renal impairment or failure, who are thus ineligible for metformin, without dose adjustment, as specified by the Asserted Patents.[1] It also provides extensive safety and efficacy data from multiple clinical studies for such patients. [redacted] Apotex's Label thus instructs physicians to prescribe its generic product in a way that would infringe, providing sufficient evidence for inducement.

Second, Apotex argues that it lacks the specific intent because its proposed product can be used "regardless of a patient's eligibility for metformin," whereas the Asserted Patents require treating a patient ineligible for metformin. D.I. 27 at 21.

[1] The patents asserted in this action are: U.S. Patent Nos. 9,486,526 ("the '526 Patent") and 10,034,877 ("the '877 Patent").

But Apotex's Label directs the use of the drug for patients with severe renal impairment or renal failure, without requiring dose adjustment. Both the specifications and claims of the Asserted Patents, as well as the publicly available metformin label, make clear that metformin is contraindicated in patients with severe renal impairment or renal failure. Using alternative terminology to describe the same patient population makes no difference on how Apotex's product will be used by healthcare providers and does not negate Apotex's intent.

Third, Apotex's argument that the existence of substantial non-infringing uses for its product precludes a finding of specific intent for induced infringement also fails. It is contrary to the well-settled precedent that "a person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses." *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd*., 887 F.3d 1117, 1133 (Fed. Cir. 2018). The instructions and information in Apotex's generic label that "would inevitably lead some physicians to infringe" is sufficient to establish the requisite intent for inducement, and Apotex's invocation of alleged substantial noninfringing use simply is not relevant. *Id*. at 1132.

Fourth, regarding contributory infringement, Apotex cannot establish at the pleading stage that its product has a substantial noninfringing use. "In assessing whether an asserted noninfringing use [is] 'substantial,'" the fact finder "consider[s] not only the use's frequency, but also the use's practicality, the invention's intended

purpose, and the intended market." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010). The parties have not yet begun discovery, including investigations into whether any noninfringing use can be considered substantial. Because "the pleading stage of this case is not the time to conclusively determine … substantial non-infringing use," *Rhodes Pharms. L.P. v. Indivior, Inc*., No. CV 16-1308, 2018 WL 326405, at *9 (D. Del. Jan. 8, 2018), Apotex's argument on contributory infringement also fails.

Apotex asks the Court, at the pleading stage, to make a ruling despite contested factual issues, on an incomplete factual record, and without allowing Boehringer to take discovery or serve expert reports according to the Court's scheduling order. However, Boehringer's Complaint, based on Apotex's Label, with its instructions and clinical data for the use of its generic product by patients with severe renal impairment or renal failure supports a plausible claim of infringement. Apotex's motion thus should be denied.

III. STATEMENT OF FACTS

A. Type 2 Diabetes Mellitus ("T2DM")

T2DM is a metabolic disorder marked by high blood sugar levels. D.I. 2, Ex. 1 at 1:31-36. It is a progressive disease that causes many complications and is a leading cause of kidney failure. *Id.* at 1:17-25. This creates a significant challenge for the many T2DM patients with renal impairment because almost all oral T2DM

drugs are either unsuitable or require dose adjustments, necessitating continuous renal function monitoring. Tradjenta® fills in this crucial gap, as one of the few T2DM drugs that can be used safely in patients with severe renal impairment or failure without the need for dose adjustment.

B. Metformin and Glucophage® Label

Metformin is an antidiabetic drug first sold under the brand name of Glucophage®. D.I. 25, Ex. 1 (Glucophage® label) at 1. It is a first-line therapy for T2DM, but metformin is contraindicated against "[s]evere renal impairment" or renal function below that level. D.I. 25, Ex. 1 at 1.

C. Tradjenta® and the Asserted Patents

Boehringer holds New Drug Application No. 201280 ("the NDA") for Tradjenta. D.I. 2 at ¶ 25. The sole active ingredient of Tradjenta is linagliptin. D.I. 15, Ex. A at 1, 17. At the FDA-approved 5 mg dose, linagliptin can be administered to patients with any degree of renal impairment without dose adjustment. *Id.* at 5.

The Asserted Patents cover, among others, methods of treating T2DM using linagliptin in patients with severe renal impairment or renal failure, who are therefore contraindicated against metformin, without dose adjustment. *See* D.I. 2, Ex. 1 ('526 Patent), Ex. 2 ('877 Patent).

D. Metformin's Contraindication Against Patients with Severe Renal Impairment or Failure Is Known

It is publicly known that metformin is contraindicated in patients with severe renal impairment or renal failure. The specifications of the Asserted Patents note that "[metformin] is contraindicated in patients with renal disease or renal impairment." D.I. 2, Ex. 1 at 1:63-66. The claims of the Asserted Patents also identify severe renal impairment or renal failure as a contraindication against metformin. '877 Patent at Claims 12-14. Likewise, metformin's label lists "[s]evere renal impairment" or renal function below that level as a contraindication. D.I. 25, Ex. 1 at 1. Thus, persons of skill in the art understand that patients with severe renal disease or renal failure are patients with contraindication against metformin.

E. Apotex's ANDA

Apotex filed ANDA No. 218552 for a generic version of Tradjenta®, relying on Boehringer's Tradjenta® NDA and proposing a label based on Tradjenta®. D.I. 2 at ¶ 29; D.I. 27 at 7.

[redacted]

[redacted]

[redacted]

F. Boehringer's Complaint

On May 9, 2023, Boehringer received a letter from Apotex indicating that Apotex intends to engage in the commercial manufacture and sale of Apotex's linagliptin tablets. D.I. 2 at ¶ 30. On June 23, 2023, Boehringer filed this suit alleging that "the Apotex ANDA Product, when used in accordance with the instructions provided in the prescribing label included in the Apotex ANDA, will cause healthcare providers or clinicians to practice a method of treating type 2 diabetes mellitus in patients with renal impairment by administering an oral dose of 5 mg per day of linagliptin to such patients without dose adjustment." *Id.* at ¶ 37. Based on such, Boehringer asserted induced and contributory infringement of the Asserted Patents. *Id.* at ¶¶ 38-57.

IV. LEGAL STANDARD

"Under Rule 12(c) … judgment will not be granted 'unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.'" *Soc'y Hill Civic Ass'n v. Harris*, 632 F.2d 1045, 1054 (3d Cir. 1980) (quoting 5 C. Wright & A. Miller, Federal Practice and Procedure, s 1368, at 690 (1969)); *see also Zimmerman v. Corbett*, 873 F.3d 414, 417 (3d Cir. 2017). "The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference." *Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 617 (D. Del. 2008). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997).

In making this determination, the Court must "accept as true all factual allegations in the pleadings and view those facts in the light most favorable to the Plaintiff." *CAP-XX, Ltd. v. Ioxus, Inc.*, C.A. No.18-849-CFC, 2020 WL 998536, at *1 n.1 (D. Del. Mar. 2, 2020); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009); *Par Pharm., Inc. v. Hospira, Inc*., C.A. No. 17-944-JFB-SRF, 2018 WL 3343238, at *4 (D. Del. May 11, 2018). A district court must also credit as true

allegations about "scientific" facts. *Mallinckrodt IP Unlimited Co. v. B. Braun Med. Inc.*, C.A. No. 17-365-LPS, 2018 WL 2254540, at *1 (D. Del. 2018).

V. ARGUMENT

A. Apotex Is Not Entitled to Judgment as a Matter of Law of No Induced Infringement

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). A finding of inducement requires establishing "that the defendant possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co*., 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc* in relevant part) (internal quotation omitted).

Apotex cannot show that it does not induce infringement of the Asserted Patents. To the contrary, as Boehringer has alleged in its Complaint, Apotex's ANDA product, when used in accordance with the instructions provided in its Label, will result in infringement.

1. *Apotex's ANDA product, when used in accordance with the instructions provided in the proposed Label, will result in direct infringement*

Following the instructions on Apotex's Label would lead healthcare providers and patients to use Apotex's generic drug in a manner that infringes the Asserted Patents. In the context of patents for methods of treatment involving a drug product, "[t]he pertinent question is whether the proposed label instructs users to perform the patented method." *AstraZeneca*, 633 F.3d at 1060. Specifically, "evidence that the

product labeling that Defendants seek ***would inevitably lead some physicians to infringe*** establishes the requisite intent for inducement". *Lilly*, 845 F.3d at 1369 (emphasis added); *see also AstraZeneca*, 633 F.3d at 1060 (finding specific intent where the label "would inevitably lead some consumers to practice the claimed method").

Courts have also held that "[e]ven where a proposed label does not explicitly track the language of a claimed method, a package insert containing directives that will 'inevitably lead some consumers to practice the claimed method' provides sufficient evidence for a finding of specific intent." *Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 673-74, 680 (D. Del. 2016), *aff'd sub nom. Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636 (Fed. Cir. 2017) ("it is sufficient that Defendants' labels will encourage some physicians to prescribe dronedarone to patients with risk factors and will thus inevitably lead to infringing uses."); *see also Impax Lab'ys, Inc. v. Actavis Lab'ys FL, Inc.*, No. CV 15-6934 (SRC), 2018 WL 1863826, at *12 (D.N.J. Apr. 18, 2018) ("The lesson of *Lilly* is that the key question is whether the label teaches performance of an infringing use, and that ***evidence of the prevalence of that infringing use is not part of that analysis***.") (emphasis added.)

Boehringer has set forth a plausible claim that Apotex's Label instructs users to perform the patented method and that such instructions will inevitably lead some

consumers to practice the claimed methods. For example, like many other claims of the Asserted Patents, claim 13 of the '877 patent recites a method for treating T2DM in patients who have severe renal impairment or end-stage renal disease and thus are contraindicated against use of metformin:

> **13**. A method of treating 2 diabetes mellitus in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising
> orally administering to the patient 5 mg of [linagliptin] per day,
> wherein the contraindication is selected from the group consisting of severe renal impairment or end-stage renal disease,
> wherein no adjustment of the daily dose is required in patients with severe renal impairment or end-stage renal disease.

D.I. 2, Ex. 2 at 30:49-60. As alleged in the Complaint, Apotex's Label provides specific instructions that satisfy each of the elements of claim 13. Apotex does not challenge most of the elements in its motion.

a. *Unchallenged elements*

Apotex does not challenge that its generic drug satisfies the elements of "[a] method of treating 2 diabetes mellitus," "orally administering to the patient 5 mg of [linagliptin] per day," and "wherein no adjustment of the daily dose is required in patients with severe renal impairment or end-stage renal disease." *See generally*, D.I. 27. [redacted]

[redacted]

b. *Challenged elements*

Contrary to Apotex's assertion, Apotex's Label encourages physicians to treat patients "for whom metformin therapy is inappropriate due to at least one contraindication against metformin" and "wherein the contraindication is selected from the group consisting of severe renal impairment or end-stage renal disease," as required by this claim. At the very least, there is a question of fact that precludes judgment on the pleadings.

[redacted]

[redacted]

As such, Apotex's Label encourages physicians to administer linagliptin to patients with severe renal impairment, which, as the '877 Patent notes (and as, *e.g.*, the label for metformin explicitly states (D.I. 25, Ex. 1 at 1)), is a contraindication against metformin.

In summary, the instructions and information provided in Apotex's Label for healthcare providers and patients, if followed, would result in direct infringement of claim 13. This claim is used here for illustrative purposes, and other claims of the Asserted Patents would also be infringed for similar reasons. At the very least, the way that healthcare providers and patients would interpret Apotex's Label is a disputed factual issue that should be decided after discovery.

2. *Apotex's Label Encourages, Recommends, or Promotes an Infringing Use of Apotex's ANDA Product*

Apotex's inclusion of instructions and information in its Label that would lead to infringement when followed (*see supra*), establishes specific intent to induce infringement under the controlling case law. At the very least, there is a question of fact that precludes judgment on the pleadings.

[redacted] But the determination of whether a label induces infringement is not based on the content that has been removed, but rather on the remaining instructions. *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc*., 7 F.4th 1320, 1327-29 (Fed. Cir. 2021), *cert. denied sub nom. Teva Pharms. USA, Inc. v. Glaxo-SmithKline LLC*, 143 S. Ct. 2483 (2023).

[redacted]

[redacted]

The cases Apotex references do not support its position. First, most of the cases were decided at the summary judgment stage or post-trial. This difference in procedural posture is significant, given the fact-intensive analysis required to evaluate induced infringement, particularly regarding specific intent.

Moreover, Apotex's cases are distinguishable on the merits. For example, Apotex points to *Takeda Pharmaceuticals* for its contention that the Federal Circuit made a distinction between simply describing an infringing mode and actively recommending or promoting it. D.I. 27 at 19. But in *Takeda*, the generic product was not approved for the method of treatment claimed to be infringed. *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp*., 785 F.3d 625, 629-30 (Fed. Cir. 2015). In *Takeda*, while the patents claimed a method for *treating* acute gout, the generic drug is indicated only for *prophylactic* use. *Id.* The generic label vaguely advised patients that "[i]f you have a gout flare while taking [the drug], tell your healthcare provider" and cautioned that the "safety and effectiveness of [the drug] for acute treatment of gout flares during prophylaxis has not been studied." *Id.* at 630. Apotex's Label goes far beyond merely describing an infringing mode. It provides dosage instructions for administering linagliptin to renally impaired patients (who are, by definition, ineligible for metformin) with no dosage

adjustment, along with clinical studies demonstrating the drug's safety and effectiveness for this use. D.I. 15, Ex. C at 6, 8, 10, 19.

Other cases Apotex relies on are similarly inapposite. In *Amarin Pharma v. Hikma Pharmaceuticals*, the court noted Amarin's reliance on the label's silence about the patented use for reducing cardiovascular risk along with a ***warning*** that mentioned patients with cardiovascular risks was not sufficient to establish specific intent. 578 F. Supp. 3d 642, 645-48 (D. Del. 2022). That stands in contrast to Apotex's Label, which provides instructions and clinical data for use of the product in an infringing manner. Similarly, in *Genetech v. Sandoz* and *Shire v. Amneal Pharmaceuticals*, the generic labels in question either offered multiple dose modification options left to the physician's discretion or made generic statements about drug intake, such as being taken "with or without food." *Genentech, Inc. v. Sandoz, Inc*., 592 F. Supp. 3d 355, 368 (D. Del. 2022); *Shire LLC v. Amneal Pharms., LLC*, No. CIV.A. 11-3781 SRC, 2014 WL 2861430, at *5 (D.N.J. June 23, 2014). [redacted]

[2] Apotex's other cases are likewise distinguishable. *See, e.g.*, *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (mere knowledge of off-label infringing use does not establish inducement); *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc*., 940 F.3d 680, 702 (Fed. Cir. 2019) (no infringement when the patented method requires three distinct treatment steps but the generic label "only

3. *Existence of Noninfringing Use Does Not Preclude a Finding of Induced Infringement*

Apotex argues that the Court should find a lack of specific intent because its generic drug is intended for use in patients "regardless of a patient's eligibility for metformin," whereas the Asserted Patents require treating a patient ineligible for metformin. D.I. 27 at 14-15, 21. Even if that were an accurate interpretation of Apotex's Label,[3] it is irrelevant: "The existence of a substantial non-infringing use does not preclude a finding of inducement." *See, e.g.*, *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1364 (Fed. Cir. 2012).

For example, in *GlaxoSmithKline*, the accused infringer, like Apotex here, argued that its "partial" label did not induce infringement because it included indication for "patients … with or without symptomatic heart failure," while the patent at issue targeted patients with heart failure. *GlaxoSmithKline*, 7 F.4th at 1329-30. The accused infringer argued this precluded a finding of inducement because its label "may encourage both infringing and noninfringing uses." *Id*. The Federal Circuit rejected this argument, finding the accused infringer's contention that a noninfringing use of a drug product must "somehow obviate[] infringement"

require[s] the first step"); *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023) (no inducement when "plaintiffs' infringement theory depends entirely on the 'Adverse Reactions' section of the defendants' ANDA labels.").

[3] As discussed above, Apotex's Label provides instructions for use by patients with severe renal impairment or renal failure (who are, by definition, not eligible for metformin treatment).

unpersuasive. *Id.* ("According to Teva, when its generic carvedilol is used to treat patients without symptomatic heart failure, there is no infringement, and thus, the label's recommended use on both types of patients somehow obviates infringement. We do not find this argument persuasive . . . ."); *see also Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd*., 887 F.3d 1117, 1133 (Fed. Cir. 2018) ("Section 271(b), on inducement, does not contain the substantial noninfringing use restriction …. Thus, a person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses.") (internal quotations omitted); *Sanofi v. Watson Lab'ys Inc*., 875 F.3d 636, 646 (Fed. Cir. 2017) (rejecting argument that substantial noninfringing uses preclude specific intent). The law is clear that "evidence that the product labeling that Defendants seek would inevitably lead ***some*** physicians to infringe establishes the requisite intent for inducement" and that "evidence of the ***prevalence*** of that infringing use is not part of that analysis." *Lilly*, 845 F.3d at 1369 (emphasis added); *Impax Lab'ys*, 2018 WL 1863826 at *12.

Apotex's reliance on *Warner-Lambert*—an ***off-label*** use case where neither the branded product nor the accused generic drug was approved for the method of use claimed in the patent in issue—is similarly misplaced. As the Federal Circuit has explained, the court in *Warner-Lambert* merely "declined to 'infer' intent to induce infringement" "[i]n the context of that off-label use case where there were 'substantial noninfringing uses.'" *Vanda*, 887 F.3d at 1133. Indeed, the Federal

Circuit in *Vanda* held the opposite, noting that "the proposed label itself recommends infringing acts" and finding "even if the proposed ANDA product has substantial noninfringing uses, West-Ward may still be held liable for induced infringement." *Id.*

4. *Fact Disputes Preclude Judgment on the Pleadings of Noninfringement*

"Under Rule 12(c) … judgment will not be granted 'unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.'" *Soc'y Hill Civic Ass'n v. Harris*, 632 F.2d 1045, 1054 (3d Cir. 1980) (quoting 5 C. Wright & A. Miller, Federal Practice and Procedure, s 1368, at 690 (1969)). Apotex cannot make this showing.

The "question of specific intent to induce infringement is a question of fact for the finder of fact" and is "particularly inappropriate for resolution by [judgment as a matter of law] because evaluating state of mind often requires the drawing of inferences from the conduct of parties about which reasonable persons might differ." *Impax Lab'ys*, 2018 WL 1863826 at *12 (citing *Justofin v. Metro. Life Ins. Co.*, 372 F.3d 517, 524 (3d Cir. 2004)). Here, Apotex's motion turns on this very issue of intent: does Apotex *intend* to encourage physicians to prescribe its generic drug to patients for whom metformin is contraindicated due to renal impairment in an infringing manner? Boehringer has presented plausible factual allegations that Apotex has this intent. D.I. 2 at ¶¶ 45-46; D.I. 25 at ¶¶ 75-80; *see supra* Section

V.A.2. On a motion for judgment on the pleadings, these allegations must be accepted as true and viewed in the light most favorable to the plaintiff, *see CAP-XX*, 2020 WL 998536, at *1 n.1, and Apotex's own spin on its Label cannot be credited over Boehringer's allegations.

B. Apotex Is Not Entitled to a Judgment as a Matter of Law of No Contributory Infringement

Substantial noninfringing use is an intensely factual inquiry not suitable for determination at the pleading stage. *Rhodes*, 2018 WL 326405 at *9 ("[T]he pleading stage of this case is not the time to conclusively determine … substantial non-infringing use . . . ."). "In assessing whether an asserted noninfringing use [is] 'substantial,'" the fact finder "consider[s] not only the use's frequency, but also the use's practicality, the invention's intended purpose, and the intended market." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010). Accordingly, in *Rhodes*, the court declined to determine substantial, non-infringing use "[w]ithout further evidence and explanation" at the pleading stage, despite the generic label "expressly provid[ing] for an alternate" method of use. *Rhodes*, 2018 WL 326405 at *9.

Here, Apotex is asking the Court to make a factual finding on substantial noninfringing use based on an incomplete factual record and Apotex's disputed allegations. But at this stage, the Court must credit Boehringer's allegations that Apotex's generic product "is not [a] staple article[] of commerce or commodit[y] of

commerce suitable for substantial noninfringing use." D.I. 25 at ¶¶ 75-80; D.I. 2 at ¶ 43. Apotex's own interpretation of the Label to the contrary at most spawns material disputes of fact as to, for example: how physicians would understand Apotex's Label, and the practicality and frequency of alleged noninfringing use. Apotex's request that this Court must affirmatively find substantial noninfringing use as a matter of law should be rejected.

VI. CONCLUSION

Boehringer respectfully requests that Apotex's Motion for Judgment on the Pleading be denied.

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January 17, 2023

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/s/ Megan E. Dellinger

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